CLAIMS

1. A method for the treatment of a severe form of bone loss diseases in a patient in need of such treatment which comprises administering an effective amount of a cathepsin K inhibitor to the patient.

2. The use of a cathepsin K inhibitor in the preparation of a medicament for the treatment of a severe form of bone loss diseases.

3. A pharmaceutical composition which incorporates as an active agent a cathepsin K inhibitor for use in the treatment of a severe form of bone loss diseases.

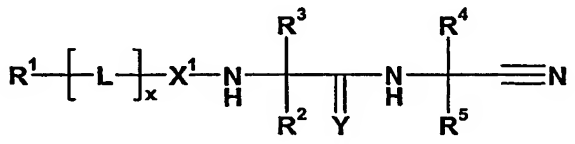
4. A method, use or composition according to any preceding claims, wherein the cathepsin K inhibitors are used to stimulate bone growth in a patient in need of such a treatment.

6. A method, use or composition according to any preceding claims, wherein the diseases are a severe form of osteoporosis, osteoarthritis or bone metastasis.

7. A method, use or composition according to any preceding claims, wherein the disease is severe osteoporosis.

8. A method, use or composition according to any preceding claims, wherein the disease is severe osteoporosis in postmenopausal women.

9. A method, use or composition according to any preceding claims, in which the cathepsin K inhibitor is selected from the following compounds of formula V or a pharmaceutically acceptable salt thereof, or any hydrate thereof



(V)

wherein

R^1 is optionally substituted (aryl, aryl-lower alkyl, lower alkenyl, lower alkynyl, heterocyclyl or heterocyclyl-lower alkyl);

R^2 and R^3 together represent lower alkylene, optionally interrupted by O, S or NR^6, so as to form a ring with the carbon atom to which they are attached, and R^6 is hydrogen, lower alkyl or aryl-lower alkyl;

R^4 and R^5 are independently H, or optionally substituted (lower alkyl or aryl-lower alkyl), $-C(O)OR^7$, or $-C(O)NR^7R^8$, wherein R^7 is optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl), and R^8 is H, or optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl); or

R^4 and R^5 together represent lower alkylene, optionally interrupted by O, S or NR^6, so as to form a ring with the carbon atom to which they are attached, and R^6 is hydrogen, lower alkyl or aryl-lower alkyl; or

R^4 is H or optionally substituted lower alkyl and R^5 is a substituent of formula $-X^2-(Y^1)_n-(Ar)_p-Q-Z$ wherein

Y^1 is O, S, SO, SO_2, $N(R^6)SO_2$, $N-R^6$, SO_2NR^6, $CONR^6$ or NR^6CO;

N is zero or one;

P is zero or one;

X^2 is lower alkylene: or when n is zero, X^2 is also C_2-C_7-alkylene interrupted by O, S, SO, SO_2, NR^6, SO_2NR^6, $CONR^6$ or NR^6CO, and R^6 is hydrogen, lower alkyl or aryl-lower alkyl;

Ar is arylene;

Z is hydroxyl, acyloxy, carboxyl, esterified carboxyl, amidated carboxyl, aminosulfonyl, (lower alkyl or aryl-lower alkyl)aminosulfonyl, or (lower alkyl or aryl-lower alkyl)sufonylaminocarbonyl; or Z is tetrazolyl, triazolyl or imidazolyl;

Q is a direct bond, lower alkylene, Y^1-lower alkylene or C_2-C_7-alkylene interrupted by Y^1;

X^1 is $-C(O)-$, $-C(S)-$, $-S(O)-$, $-S(O)_2-$, or $-P(O)(OR^6)-$, and R^6 is as defined above;

Y is oxygen or sulphur;

L is optionally substituted –Het-, -Het-CH_2- or $-CH_2$-Het-, and Het is a hetero atom selected from O, N or S; and

X is zero or one; and

aryl in the above definitions represents carbocyclic or heterocyclic aryl.

10. A method, use or composition according to any preceding claims, in which the cathepsin K inhibitor is N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide, or a pharmaceutically acceptable salt thereof, e.g. the maleate form, or any hydrate thereof.

11. A pharmaceutical composition comprising less than 50.1 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide or a pharmaceutically acceptable salt thereof wherein the amount of the base form is less than 50.1 mg.

12. The pharmaceutical composition according to claim 11 comprising less than 64.2 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide maleate.

13. All novel compounds, processes, pharmaceutical compositions, methods and uses substantially as hereinbefore described with particular reference to the Examples.